

Application No. 10/680,459

Docket No.: NY-HUBR 1230-US

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Entry of the amendment is requested.

With respect to the objection to the specification, the Examiner states "(T)he specification still contains a lot of errors and still needs correction." At page 3, the only details provided are:

"The way that AWD 131-138 is written should be uniform throughout the specification. In some instances it is written as AWD 131 138. There are also several grammatical errors, as well as spelling errors throughout the specification that should be changed."

Applicants have reviewed the specification carefully; however, if the Examiner does not specify precisely what she considers an error, applicants cannot respond completely.

Claim 15 has been corrected.

The Examiner has rejected claims 12-17 and 19, i.e., all pending claims, as allegedly being obvious under 35 U.S.C. § 103. Claims 12-15 and 19 were rejected under 35 U.S.C. § 103 in view of Bialer plus Ross plus French. The Examiner adds Thomas to reject claims 16 and 17.

Applicants have studied the rejections, and traverse.

With respect to claims 12-15 and 19, the Examiner states that:

"Bailer et al. teach that AWD 131-138 treats audiogenic clinic seizures in genetic models of epilepsy (meeting the limitation of claim 12; pg. 12, Section 2.1.1.1)."

This discussion of Bailer, however, quotes the reference incompletely:

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"AWD 131-138 is active in primary screening tests for anticonvulsant activity in mice and rats using the maximal electroshock test (MES), and supramaximal stimulation with chemical convulsants such as pentylenetetrazyl and bicuculline. Audiogenic clonic seizures in genetic models of epilepsy are potently inhibited."

The form of epilepsy treated - in mice and rats (not dogs) was caused by a chemical convulsant. The cause was known. Therefore, this is NOT idiopathic epilepsy. Inhibiting clonic seizures means that a symptom of the disease was reduced, the disease being chemically induced epilepsy.

With respect to dogs, experiments were carried out, again with PTZ - which is not idiopathic epilepsy.

This is very important because, according to French, cited by the Examiner:

"Patients with idiopathic generalized epilepsy syndromes, including absence, generalized tonic-clonic, and juvenile myoclonic epilepsy, usually have more than one seizure type."

French then summarizes new "AEDs" at page S211, and points out, essentially, that a drug efficacious against tonic-clonic seizures has "hit or miss" efficacy against the other symptoms of idiopathic epilepsy. Please see Table 2, at page S211. The Examiner's characterization of French as teaching "clonic or tonic clonic seizure activity" and "absence epilepsy" as "forms of idiopathic epilepsy" is not accurate. What French states is that:

"Patients with Idiopathic generalized epilepsy syndromes, including absence, generalized tonic-clonic..."

Tonic-clonic seizure and absence are symptoms of idiopathic epilepsy. They are not forms of idiopathic epilepsy. Many conditions share symptoms. The Examiner has not shown that presence of a particular syndrome de facto means that a subject has

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idiopathic epilepsy. Rather, when French is taken as a whole, as is required by law, it teaches that a drug which is effective against one symptom is not necessarily effective against another.

As such, the fact that Ross teaches that AGS animal subjects exhibit tonic-clonic seizure does not mean that AGS is idiopathic epilepsy. In any event, "AGS is induced by intense sound exposure during post natal development," as per the abstract. In other words, the cause is known. AGS cannot be an idiopathic condition.

The fact is, given that Bialer and Ross teach conditions with known causes renders them inapplicable to idiopathic diseases. French teaches that the ability to treat a symptom, such as tonic-clonic seizures, which is associated with both idiopathic conditions, is not necessarily going to be useful in others.

The combination of the three references falls far short of, establishing a prima facie case, and it is thus submitted that the rejection should be withdrawn.

Thomas does not address the failings of the primary rejection. Hence, its addition does not provide sufficient information to make out a prima facie case. As such, this rejection should be withdrawn as well.

In view of the foregoing, withdrawal of the rejection and allowance of all claims 12-17 and 19 is believed proper and is urged.

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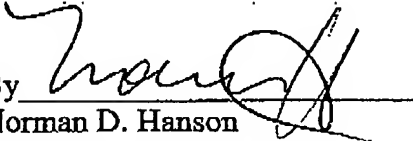
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If any fees are due, authorization is given to charge our Deposit Account No. 50-0624, under Order No. NY-HUBR 1230-US (10312533) from which the undersigned is authorized to draw.

Dated: 10/18/07

Respectfully submitted,

By 
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